

VHA PROSTHETIC CLINICAL MANAGEMENT PROGRAM (PCMP) CLINICAL PRACTICE RECOMMENDATIONS FOR UTILIZING DEEP BRAIN STIMULATORS WITHIN THE VA HEALTH CARE SYSTEM

I. PURPOSE

The purpose of the clinical practice recommendations is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective prescribing.

II. BACKGROUND

VHA's Prosthetic and Sensory Aids Service Strategic Healthcare Group was directed by the Under Secretary for Health to establish a Prosthetic Clinical Management Program (PCMP). The objectives are to coordinate the development of clinical practice recommendations for prosthetic prescription practices and contracting opportunities to assure technology uniformity and ease of access to prosthetic prescriptions and patient care that will lead to valid outcome measures and analysis for research purposes.

Any VA neurosurgeon who has been performing brain lesioning surgery to treat movement disorders can be expected to switch to deep brain stimulation (DBS) as their procedure of choice. DBS, electrical stimulation of the brain using an implanted electrode, produces a "functional" lesion within a focal area of the brain. DBS offers many potential benefits relative to ablative procedures because it produces a functional rather than structural lesion. The procedure is non-destructive and reversible. The implanted electrode causes no histological change in brain tissue. Unlike a lesion, which has a fixed, permanent effect, stimulation parameters (amplitude, pulse width, pulse frequency, and stimulation pattern) of a DBS system can be adjusted via non-invasive telemetry to change the volume and distribution of tissue stimulation to meet the changing needs of each patient (e.g., as required by disease progression). Importantly, the incidence of permanent complications following implantation of unilateral or bilateral DBS electrodes is lower than that associated with unilateral or bilateral lesioning procedures, making stimulation a viable alternative for management of symptoms. Reprogramming the DBS systems can usually eliminate side effects that may occur as a result of stimulation. Targets within the brain are similar, in general, for both ablative and stimulation therapies. Surgery is offered to those patients who have persistent disabling symptoms despite comprehensive medication therapy, or who have intolerable medication-related side effects that preclude effective medication therapy, thus the VA system can expect a new demand for these expensive but very helpful implants.

III. MEDICAL CRITERIA

The current FDA approved indications for deep brain stimulation are:

- *Essential tremor* – Unilateral or bilateral stimulation of the Vim nucleus is indicated for tremor that is not controlled by medications and is disabling to the patient.
- *Parkinson's disease* – Bilateral or unilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) is indicated for adjunctive therapy in reducing some of the symptoms of advanced, levodopa-responsive Parkinson's disease that are not adequately controlled with medication. These symptoms include but are not limited to tremor, bradykinesia, rigidity, dystonia, dyskinesias, and gait disturbance.

Off Label Use – should be based on best available medical evidence.

IV. CONTRAINDICATIONS

The following are activities contraindicated after a stimulator is implanted:

- Diathermy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death. Diathermy is further prohibited because it can also damage the neurostimulation system components resulting in loss of therapy, requiring additional surgery for system explantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned "on" or "off." Patients should inform all their health care professionals that they should not be exposed to diathermy treatment.
- Patients who will be exposed to Magnetic Resonance Imaging (MRI) using a full body radio-frequency (RF) coil or a head transmit coil that extends over the chest area. Refer to the product labeling for comprehensive safety information on the use of MRI in patients with implanted DBS systems.

V. IMPLANTING CENTERS

Funding for the implants will be provided by the Prosthetic and Sensory Aids

Service through the centralized funding for prosthetics. These devices are to be implanted at the Parkinson's Disease Research, Education, and Clinical Centers (PADRECCs) and other VA medical centers with the necessary personnel, equipment, and expertise.

1. For the purposes of this Clinical Practice Recommendation, the facility referring the implant candidate is the *referring facility*. The facility providing the implant services is the *host facility*.
2. The host facility is responsible for paying the cost of evaluation, implantation surgery, anesthesia, inpatient costs, ancillary services, other services that may be medically necessary for the management of the patient, follow-up evaluations, and other visits as may be required to ensure that the patient obtains maximum benefit from the implant.
3. For VHA patients, the referring facility will pay for travel to the host facility and the host facility will pay for lodging and return travel in accordance with VHA Policy on "travel and lodging for patients, spouses and significant others".
4. The host facility is responsible for paying the cost of the implant device, accessories, repairs, and replacements. VHA Parkinson's Disease Research, Education, and Clinical Centers (PADRECCs) and other VA medical centers with the necessary personnel, equipment, and expertise will receive funding for the implant devices from PSAS centralized funds.
5. The host facility is responsible for coordinating all evaluations, tests, surgical and radiological services, ancillary services, training sessions, and other services that are medically necessary. Where appropriate, the referring facility may provide initial evaluations, medical tests, and radiology exams as necessary to determine candidacy. However, the host facility is responsible for evaluating the completeness or adequacy of clinical data provided by the referring facility.

Contact numbers for the PADRECC's are listed below:

Houston PADRECC – (713) 794-7841
Northwest (Portland/Seattle) PADRECC – Portland (503) 721-1091
Seattle (206) 277-4560
Philadelphia PADRECC – (215) 823-5934 or (888) 959-2323
San Francisco PADRECC - (415) 379-5530
Southeast (Richmond) PADRECC – (804) 675-5931
Southwest (West Los Angeles) PADRECC – (310) 478-3711 x48001

VI. REFERENCES

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APPROVED/DISAPPROVED:



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Under Secretary for Health

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Date